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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,447	12/02/1998	WERNER LUBITZ	P564-8013	3704

7590 10/06/2003

ARENT FOX KINTNER PLOTKIN & KAHN PLLC  
1050 CONNECTICUT AVENUE, N.W.  
SUITE 600  
WASHINGTON, DC 20036-5339

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

33

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/117,447

Applicant(s)

LUBITZ ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-24, 26, 28-30, 32-34 and 37-66 is/are pending in the application.
- 4a) Of the above claim(s) 21-24, 26, 28-30, 32-34, 37-45 and 48-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19, 20, 46, 47 and 58-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

1. Applicants' amendment filed July 14, 2003 is acknowledged and has been entered. Claims 1, 14, 15, 59, 60, 62 and 63 have been amended. Claims 1-17, 19, 20, 46, 47 and 58-66 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains claims 21-24, 26, 28-30, 32-34, 37-45, and 48-57 are drawn to an invention/species nonelected with traverse in Paper No. 8 and 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See M.P.E.P. § 821.01.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 58 and 61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7, 8, 10 and 12 of copending Application No. 09/463402. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a process for producing an S-layer protein or a recombinant S-layer protein comprising a heterologous protein, which can be any protein. The applications use the same nucleic acid sequence that encodes the S-layer protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1-17, 19, 20, 46, 47 and 58-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 7, 8, 10 and 12 of copending Application No. 09463402 in view of Deblaere et al. The copending application teaches a process for producing an S-layer protein or a recombinant S-layer protein comprising a heterologous protein, which can be any protein. The applications use the same nucleic acid sequence that encodes the S-layer protein as well as the use of *E. coli*

as the host cell. The copending does not specifically teach the specific use of the presently claimed heterologous or insertions in to the S-layer protein.

However, Deblaere et al teach a host cell which is provided with an S-layer comprising a fusion polypeptide consisting essentially of the S-layer protein and a heterologous polypeptide (abstract; p. 6; claims). Deblaere et al teach that the gene for the S-layer protein includes strong promoter sequences, signal peptide coding sequences as well as a transcription termination sequence (p. 2). The prior art teaches recombinant DNA molecules that include a SLP system capable of expressing and presenting a fusion polypeptide in a wide variety of bacteria (p. 5). Deblaere et al teach that the insertion or heterologous protein can be a physiologically active polypeptide such as an enzyme, a polypeptide drug or a cytokine (interferon), foreign epitope or polypeptide immunogen, etc (p. 9). The immunogen can be an antigen of a pathogen such as a virus, bacterium, fungus, yeast or parasite (pp. 9-10). Further, the prior art teaches expression vectors and suitable host cells as well as methods of producing the proteins (p. 10-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the methods/processes as taught by both the copending application (09/463402) and Deblaere et al with the reasonable expectation of success of obtaining a process to produce pure S-layer protein, a recombinant S-layer protein or a fusion protein comprising the S-layer protein having an insertion of a heterologous polypeptide as presently claimed. The co-pending application sets forth nucleotide sequence of the S-layer protein while both references provide the process methods, cells, and vectors. Deblaere et al provides the motivation and suggestion to insert foreign or heterologous protein (DNA) into the DNA of the S-layer for the purpose of making fusion proteins that are expressed. It is

noted that the prior art does not specifically teach the insertion at the specific positions that are set forth in claim 16; however it would have been obvious to a person of ordinary skill in the art at the time the invention was made to insert the foreign DNA at any cleavage site that would still allow for the assembly of the S-layer protein. The claimed invention is prima facie obvious in view of the teachings of co-pending application (09/463402) taken with Deblaere et al, absent any convincing evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

*These provisional rejections are being maintained for the reasons of record. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. Applicants have asserted that the instant application and the 09/463402 application do not share a common assignee as required under MPEP 706.02(l)(2). Although the applications are not commonly assigned, they have at least one common inventor and therefore these provisional rejections are proper (see MPEP 804).*

The rejections are maintained for the reasons of record. Applicant's arguments filed July 14, 2003 have been fully considered but they are not persuasive. It is noted that Application 09/463402 is now issued US Patent 6596510. Applicants have asserted that issued patent 6586510 is a later developed improvement of the invention disclosed in the present application. The improvement disclosed in the issued patent concerns the expression of S-layer proteins in targeted compartment using a signal sequence. Applicants have asserted that the expression of S-layer proteins in specific compartments is not

disclosed in the present application and would not have been obvious in view of the disclosure in the present application since the required signal sequences are not disclosed. However, claim 3 recites that the protein isolated from the interior of the host cell in the form of an assembled S-layer structure; this would appear to be a signal sequence that has directed the protein into a compartment (the interior of the host cell). This would appear to be the same or an obvious variant of the asserted improvement recited in the issued patent. Further, claim 14 uses a signal peptide, which would direct the proteins into a specific compartment.

5. Claims 15, 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuen et al, 1994.

It is noted that this rejection was previously set forth for all claims and withdrawn; however please note that the present rejection is only for product (i.e. nucleic acid) claims 15, 62 and 63.

Claims 15, 62 and 63 are directed to an nucleic acid encoding a full-length S-layer protein, the nucleic acid sequence comprising SEQ ID NO: 1.

Kuen et al discloses a nucleic acid sequence that encodes an S-layer protein (abstract; p. 116, col. 1). Kuen et al disclose the nucleotide sequence including signal sequence of the *sbs* gene, which encodes the S-layer protein (p. 117, col. 2; figure 2; table 1; p. 119, col. 2). The prior art discloses a 100% match with the S-layer protein (figure 2). It is noted that the claims, 15, 62 and 63, are directed to a product (i.e. nucleic acid), not a process of production. Further, the claims do not define the source of the S-layer protein or that it must be S-layer protein from a particular bacterium. Kuen et al anticipates the claimed invention.

The rejection is maintained for the reasons of record. Applicant's arguments filed July 14, 2003 have been fully considered but they are not persuasive. Applicants have asserted that Kuen et al does not disclose an isolated full-length nucleic acid sequence. Applicants have asserted that Kuen isolated three overlapping fragments, which he used to predict the full-length nucleic acid sequence. However, it is noted that the claims (15, 62 and 63 are directed to products, the nucleic acid encoding the full-length of the S-layer protein, which Kuen et al appears to disclose. The claims are directed to processes of obtaining the product, but the mere product itself. The nucleic acid sequence as claimed Applicants disclose the same as in the prior art. The prior art anticipates the claimed invention absent any convincing evidence to the contrary.

6. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "within the scope of the degeneracy of the genetic code"; what does Applicants intend? This is not further defined or described in the specification. Claims 59, 60, 62 and 63 are vague and indefinite in the recitation of "obtainable"; what are the metes and bounds of this term? Is hybridization achieved?

This rejection is maintained for claim 66 as set forth above.

7. No claims are allowed.



8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

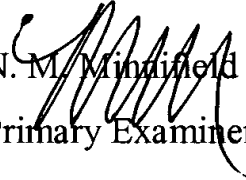
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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N. M. Minnifield  
Primary Examiner  
Art Unit 1645

NMM

September 23, 2003